

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEMS PRODUCTS LIABILITY
LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

ETHICON WAVE 6 CASES LISTED IN
EXHIBIT A

JUDGE GOODWIN

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO
EXCLUDE CERTAIN GENERAL OPINIONS OF TERENCE J. COLGAN, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude general opinions of Terence J. Colgan, M.D. (Doc. 4868).

INTRODUCTION

Dr. Colgan has practiced pathology for approximately 40 years. Ex. A hereto, Curriculum Vitae at 1. A native of Toronto, he has specialty certificates in Anatomical Pathology from both the Royal College of Physicians and Surgeons of Canada and the American Board of Pathology, and he is a member of the United States and Canadian Academy of Pathology and the International Society of Gynecological Pathologists. *Id.* A long-time member of the College of American Pathologists ("CAP"), he was awarded the CAP Educational Award in 2017. Ex. C to Pl's Motion, Expert Report at 2.

Since 1983, Dr. Colgan has specialized in gynecological pathology. *Id.* He previously served as Head of Surgical Pathology at the University Health Network in Toronto and currently is Head of the Sections of Gynecological and Cyto-pathology at the Sinai Health System in

Toronto. Ex. A hereto, CV at 2. Since 2003 he has served as a Professor in the University of Toronto Department of Obstetrics and Gynecology with a cross-appointment to the Department of Obstetrics and Gynecology. *Id.* at 1. He has contributed over 150 articles to peer-reviewed research literature

Dr. Colgan also has served as an editor or peer reviewer for many academic publications involving pathology and/or gynecology, including serving as an Editorial Board Member of the *International Journal of Gynecological Pathology* since 1992 and an Associate Editor of *Archives of Pathology and Laboratory Medicine* since 2013. *Id.* at 3-4. His significant accomplishments, including lectures, teaching appointments, memberships, and awards, are set forth in detail in his curriculum vitae. *See* Ex. A hereto.

Dr. Colgan examines approximately 5,000 pathology samples each year. Ex. C to Pl's Motion, Expert Report at 3. During his lengthy career, Dr. Colgan has examined dozens of pelvic mesh specimens, and he regularly does so as part of his practice. Ex. B hereto, 9/21/17 Dep. 25:;17-24, 157:10-158:6.

Dr. Colgan has issued a general report that sets forth expert opinions about mesh specimens and pathology. He has also critiqued the opinions of one of Plaintiffs' pathology experts, Dr. Vladimir Iakovlev. In particular, Dr. Colgan criticizes certain of Dr. Iakovlev's research articles. Ex. C to Pl's Motion, Expert Report at 12-14. He takes particular issue with an article published in the Journal of Biomedical Materials Research article on the basis that it "does not adhere to good scientific practice," because it blends observation and interpretations in a manner that suggests that his observational study was supported by experimentation and it makes an "unwarranted conclusion." *Id.* at 13-14.

Dr. Colgan also takes issues with a number of opinions set forth in Dr. Iakovlev's expert report, including:

- That mesh supposedly damages body tissue;
- His unsupported attribution of histological changes to the implantation of mesh;
- His failure to account for the low complication rates of pelvic mesh devices;
- His use of "scar plate" and "bark" terminology and contentions of clinical effects;
- His opinion that mesh contracts and compresses organs and tissues;
- His opinion that the mucosa is at risk for pain from compression;
- His assertion that "tissues surrounding the mesh are more sensitive for pain than a scar without inflammation";
- His opinion that edema causes pain;
- His speculation about muscle irritation;
- His inaccurate depiction of normal healing processes being injuries;
- His failure to account for the impact of alteration caused by formalin on specimens; and
- His opinion that an observed outer layer is, in fact, mesh degradation.

Id. at 14-20.

In their motion, Plaintiffs only appear to challenge Dr. Colgan's criticisms of Dr. Iakovlev's "research and published materials" and not his criticisms of Dr. Iakovlev's expert report. Doc. 4870, p. 4. Dr. Colgan's opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, curricula, and various other materials. Dr. Colgan is well-qualified to offer the opinions set forth in his report, his opinions are supported by a reliable methodology, and Plaintiffs' challenges lack merit.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Colgan is qualified to critique Dr. Iakovlev's opinions.

Plaintiffs present a number of challenges to Colgan's qualifications to question Dr. Iakovlev's research articles. None of Plaintiffs' arguments has merit.

A. Personal familiarity with Dr. Iakovlev

First, Plaintiffs fault Dr. Colgan for never attending any of Dr. Iakovlev's lectures and not knowing Dr. Iakovlev personally even though "they both work for the same institution." Doc. 4870, pp. 4-5. Dr. Colgan, however, explained that, although he and Dr. Iakovlev both work for hospitals within the University of Toronto Health System, that health system is a massive "umbrella" organization and they work at different hospitals within the system. Ex. B hereto, 9/21/17 Dep. 28:3-29:23, 57:22-58:12.

In any event, Plaintiffs do not explain how the mere fact that Dr. Colgan does not cross paths with Dr. Iakovlev reflects on Dr. Colgan's competence to share expert opinions in this case. If anything, this merely demonstrates that Dr. Iakovlev is not as well known or respected as Plaintiffs seek to portray him.

B. Dr. Colgan's self-identification as an expert

Plaintiffs next argue that Dr. Colgan does not hold himself out to be an expert in vaginal mesh.¹ Although Plaintiffs cite deposition testimony in which Dr. Colgan stated that “I did not hold myself out to be an expert in vaginal mesh” (Ex. B hereto, 9/21/17 Dep. 41:20-24), Plaintiffs conveniently neglect to draw the Court’s attention to Dr. Colgan’s explanation:

Q. Can you just explain what you meant by that?

A. So what I meant was, I'm not a research expert in vaginal mesh. As has been pointed out, I haven't published on it, I haven't held contracts with it, I haven't done industry contracts.

But I do -- I do have insights, as a gynecologic pathologist, into foreign tissue reactions and I am capable, as a 25-year-plus gynecologic pathologist, to assess the validity of histopathologic claims around vaginal mesh.

* * *

Q. Okay. With respect to the report you have written and issued in this case, were the opinions that you express in that report within your expertise?

A. Absolutely. I mean, many of those opinions that I've written about is about the practice of surgical pathology, histopathology in general and gynecologic pathology specifically.

Q. Then, with respect to your opinions concerning what Dr. Iakovlev has written in his report, are those opinions of yours in your response to Dr. Iakovlev, are those within your field of expertise?

A. Yes.

Id. at 157:3-158:20. *See also id.* at 55:24-56:1 (stating that he considers himself to be a peer of Dr. Iakovlev).

¹ Although Plaintiffs also argue that Dr. Colgan does not claim to have expertise “in the pathology associated with mesh utilized for herniorrhaphy or abdominal repairs” (Doc. 4870, p. 5), this is not a hernia mesh MDL; this is a pelvic mesh MDL.

Thus, Dr. Colgan does claim to have expertise to provide the opinions in this case, and his experience and credentials certainly render him well qualified. Indeed, when discussing Dr. Colgan's credentials as a board-certified gynecologic pathologist, Plaintiffs explicitly state that "Plaintiffs do not challenge his qualification as such." Doc 4870, p. 1.

C. Knowledge of number of transvaginal mesh sample submitted for pathology

Plaintiffs next challenge Dr. Colgan's opinions on the basis that he purportedly was "unable to estimate the number of vaginal mesh devices that are submitted to his Department at the University of Toronto." Doc. 4870, p. 5. Dr. Colgan stated that "I know of no database that would tell you that number," but he, in fact, later estimated approximately a dozen each year. Ex. B hereto, 9/21/17 Dep. 47:24-48:3, 157:15-158:6.

In any event, Plaintiffs fail to explain why any purported uncertainty is possibly germane to Dr. Colgan's competence to provide expert opinions. Again, Plaintiffs have conceded that they "do not challenge his qualification" as a gynecologic pathologist. Doc 4870, p. 1.

D. Failure to raise concerns internally

Plaintiffs also argue that "Dr. Colgan did not address any of his alleged 'concerns' regarding [Dr. Iakovlev's] research papers with any authoritative body at the University of Toronto" or with the publishing journals. Doc. 4870, p. 6. But Plaintiffs do not identify any requirement compelling Dr. Colgan to do so, nor do they cite any legal authority disqualifying an expert for failing to raise an internal concern about another expert.

Dr. Colgan explained why he has not done so and noted that "I cannot think of an example where an individual faculty member brought to the departmental chair's attention an

individual paper as a criticism or a red flag.” 9/21/17 Dep. 68:8-70:6. This is an argument suited for cross-examination and has no bearing on Dr. Colgan’s competence to testify.

E. Familiarity with other research articles

Finally, Plaintiffs present a number of criticisms of Dr. Colgan’s research of medical literature that are also suited for cross-examination and that do not detract from his imminent qualifications. Although Plaintiffs fault Dr. Colgan for failing to read all of Dr. Iakovlev’s research articles, they do not explain how his failure to read any certain article would in any way detract from the opinions that Dr. Colgan intends to offer. For instance, how would Dr. Colgan’s failure to read another Dr. Iakovlev article impact his opinions about the deficiencies in Dr. Iakovlev’s Journal of Biomedical Materials Research piece? Plaintiffs have not identified any articles that refute Dr. Colgan’s specific criticisms.

Plaintiffs also complain that “Dr. Colgan is unaware of the number of research articles that have cited Dr. Iakovlev’s work.” Doc. 4870, p. 6. But Plaintiffs miss the point. Dr. Colgan believes that Dr. Iakovlev published articles that included unsupported assertions. Whether other authors have subsequently cited Dr. Iakovlev’s articles blindly without verifying his assertions has no bearing on the validity of Dr. Iakovlev’s assertions or the merits of Dr. Colgan’s criticisms.

Plaintiffs also claim that Dr. Colgan “does not give any credence to the countless articles and research papers that parallel Dr. Iakovlev’s hypothesis that transvaginal mesh has a high potential for side effects.” Doc. 4870 at 6. Yet, Plaintiffs have only identified one article that they believe to be pertinent and that Dr. Colgan does not recall reviewing. *See id.* at 6-7 (citing

Feiner, B. & Maher. C., *Vaginal Mesh Contraction: Definition, Clinical Presentation, and Management*, *Obstet & Gynecol* (2010) 115(2):325-339).

Dr. Colgan explained that he performed a thorough review of the medical literature, 9/21/17 Dep. 43:13-44:3, 70:19-71:5. If every expert in this MDL were to be disqualified for their failure to read isolated articles, then it is unlikely that any experts would be competent to testify at trial. Applying Plaintiffs' argument, for instance, Dr. Iakovlev should be barred from testifying because he ignored a Canadian study that does not support his conclusions. *See* Ex. C to Pl's Motion, Expert Report at 16; Ex. B hereto, 9/21/17 Dep. 128:7-129:19.

II. Dr. Colgan has reliably opined that Dr. Iakovlev's research articles are deficient.

In pages 7-15 of their supporting brief, Plaintiffs appear to challenge Dr. Colgan's criticisms of Dr. Iakovlev's research papers on the basis that his opinions are unreliable. As set forth below, Plaintiffs' arguments lack merit.

A. *Criticisms of the structure of Dr. Iakovlev's Journal of Biomedical Materials Research article*

Plaintiffs fault Dr. Colgan for nitpicking the manner by which Dr. Iakovlev structured his *Journal of Biomedical Materials Research* article on the basis that Dr. Colgan's criticisms are "unnecessary and distracting." Doc. 4870, p. 8. But that is no basis to challenge an expert opinion.

Plaintiffs overlook that Dr. Colgan's overriding concern with the manner that Dr. Iakovlev structured the article is because it suggests that hypotheses have been validated with experimental studies. *See* Ex. C to Pl's Motion, Expert Report at 13-14. As Dr. Colgan explained: "What's important to me is that the data be presented in an objective fashion and then

the hypothesis be tested in the discussion. This paper seemingly sets out to prove degradation by use of the term, not only within the ‘Results’ section, but also in the ‘Materials and methods.’” Ex. B hereto, 9/21/17 Dep. 98:1-7. Thus, “[i]t throws into questions the derivation and interpretation of the data.” *Id.* at 99:15-20. He further refuted Plaintiffs’ suggestion as follows:

Q. And if the scientific method is followed and if there’s hypothesis and testing and results and conclusions that undergoes peer review and then subject to criticism by the general scientific or medical community, then the scientific method has been fulfilled, has it not?

A. But that was not the case here. This case did not follow the scientific method. It put forward a hypothesis and then muddled the waters throughout the “Materials and Methods” and “Results” sections.

Id. at 101:23-102:8.²

Plaintiffs suggest that Dr. Colgan’s criticisms are baseless because Dr. Iakovlev’s article was published in a peer-reviewed journal. But merely because something has been subject to peer review does not mean that it is beyond impunity and may not be subject to scrutiny through expert testimony. Dr. Colgan explained that the quality of peer review is “under serious question,” particularly with the rise of electronic medical journals. Ex. B hereto, 9/21/17 Dep. 45:18-46:9, 96:5-10. As noted by Dr. Colgan:

I’m not acquainted with the journal, but I have great concerns about any journal, which even in the Materials and Methods section, allows a section to be called “Measurement of degradation layer thickness” before the presentation of any results whatsoever, which is in flagrant violation of the initial question which is being asked: Is there degradation.

² As noted by Dr. Colgan, Dr. Iakovlev’s research “is highly biased to those cases which have failed by the nature that the vaginal mesh has been excised. So when he makes a stated about ‘vascular compartments’ or ‘edema can lead to’, he really doesn’t have a control group when he looked at those features, ‘vascular compartments’ and ‘edema’, to know whether to – whether those so-called descriptions of these areas are really associated with the symptomology that he conjectures is ascribed to them. He doesn’t have a suitable alternative group without failure.” Ex. B hereto, 9/21/17 Dep. 159:23-160:10; *see also id.* at 163:9-164:7.

And then, within their “Materials and methods” section, they have already concluded that there is a degradation layer.

Id. at 96:15-25.

The jury should be allowed to determine whether Dr. Colgan’s criticisms of Dr. Iakovlev’s work are valid.

B. Reliance on Australian and New Zealand position papers

Plaintiffs also claim that Dr. Colgan’s opinions are unreliable on the basis that he relies on a May 2017 position paper of the Royal Australian and New Zealand College of Obstetricians and Gynecologists (“RANZOG”). Ex. C to Pl’s Motion, Expert Report at 15 (citing Ex. C hereto). Plaintiffs cite no authority for the proposition that it is improper for an expert to rely on an international publication. Indeed, many of Plaintiffs’ own experts have done so in this litigation.

Plaintiffs incorrectly claim that “there is no evidence that this paper represents the general opinion of medical doctors in the United States.” Doc. 4870, p. 9. But Dr. Colgan’s expert report explicitly states, with supporting references, that “[t]his is an opinion that is shared by many other organizations, including the American Urogynecologic Society (AUGS); Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU); American College of Obstetricians and Gynecologists; Society of Gynecologic Surgeons; and Women’s Health Foundation.” Ex. C to Pl’s Motion, Expert Report at 15.

Finally, although Plaintiffs argue that the RANZOG position paper “has nothing to do with mesh degradation or mesh pathology,” Dr. Colgan explained that “[m]y purpose in citing this paper was to put the context of current mesh use within the medical profession in order to give a context to Dr. ‘I’”s research and opinions” and to illustrate that Dr. Iakovlev’s anti-mesh

sentiment is counter to the widespread sentiment of pelvic surgeons who actually treat pelvic dysfunctions. Ex. B hereto, 9/21/17 Dep. 126:7-24.

C. Alleged “cherry-picking”

Finally, Plaintiffs claim that it is somehow improper for Dr. Colgan to “cherry-pick” certain parts of Dr. Iakovlev’s research article that he has criticized. Doc. 4870, p. 10. According to Plaintiffs, “Dr. Colgan employs a ‘pick and choose’ method, with regards to Dr. Iakovlev’s research paper, to focus only on certain parts of the research paper he finds questionable.” *Id.* Plaintiffs completely misunderstand the admonition against cherry-picking.

It is unreliable for an expert to cherry-pick data to support an opinion. *See, e.g., EEOC v. Freeman*, 778 F.3d 463, 469 (4th Cir. 2015) (cited by Plaintiffs at Doc. 4870, p. 10). Here, Plaintiffs do not accuse Dr. Colgan of cherry-picking data to support his criticisms of Dr. Iakovlev’s article; instead, they claim that it is somehow improper for Dr. Colgan to take issue only with selective portions of Dr. Iakovlev’s article. In other words, Plaintiffs apparently take the position that Dr. Colgan may not criticize any aspect of Dr. Iakovlev’s article unless he takes issue with all aspects of Dr. Iakovlev’s article. Such a proposition is silly on its face and unsupported by the law.

Plaintiffs also claim that it is inconsistent for Dr. Colgan to criticize Dr. Iakovlev’s observational study while crediting the observational study in Hill, et al., *Histopathology of excise midurethral sling mesh*, *Int. Urogyn. J.* (2015) 26:591-595. *See* Ex. D hereto. Although Plaintiffs claim that both studies “adhere to the same approach and methodology,” (Doc. 4870, p. 12), Dr. Colgan completely refuted this during his deposition:

Q. Okay. Now if we could go back to the Hill paper, the "Histopathology of excised midurethral sling mesh", which is Exhibit 11.

A. Yes.

Q. This is also an observational study, is it not?

A. Yes, it is.

Q. If you look at "Methods" in the abstract, they describe this as:

"...a retrospective case-control study of women who underwent excision of midurethral sling mesh between 2008 and 2013."

Correct?

A. Mm-hmm. Correct.

Q. Dr. Iakovlev's paper is a retrospective study, also; correct?

A. Correct.

Q. Now, the utilizing your language in your expert report that we just read from, the same "potential confounding [factor] variables which can rarely be fully controlled or eliminated", as you apply to Dr. Iakovlev's paper, also apply to the Hill paper which is your reference 10 that you are relying upon for your expert opinion; correct?

MR. DAVIS: Object to the form.

THE WITNESS: The Hill paper did go further, though, and had good clinical data to put together with their histopathologic obligations.

BY MR. RESTAINO:

Q. And you understand that there are experts on the other side who also believe that Dr. Iakovlev's paper has good clinical data to go with his results?

MR. DAVIS: Object to the form.

THE WITNESS: With respect to the paper that we are discussing of his, I do not see clinical data which is evident in the Hill paper.

BY MR. RESTAINO:

Q. Okay. You agree that they are both retrospective analyses?

A. Yes.

Q. You agree that they both have potential for confounding variables in that they are, (a), observational studies; (b), retrospective studies with all the epidemiological biases that that entails; correct?

MR. DAVIS: Object to the form.

THE WITNESS: They share characteristics of observational and retrospective studies, but the Hill paper has gone further and collected clinical data and grouped them into three groups, which is absent from Iakovlev's paper.

Ex. B hereto, 9/21/17 Dep. 88:19-90:22 (emphasis added).

Conveniently, Plaintiffs chose not to draw the Court's attention to this testimony in their brief. Dr. Colgan's explanation for distinguishing the two studies is perfectly sound, and Plaintiffs are free to explore the issue on cross-examination.

Plaintiffs finally contend that "Dr. Colgan attempts to manipulate Dr. Iakovlev's findings" by selectively quoting a portion of Dr. Iakovlev's article indicating that "the exact mechanisms of . . . [mesh] complications are yet to be understood." Doc. 4870, p. 13 (quoting Ex. C to Pl's Motion, Expert Report at 14. According to Plaintiffs, Dr. Colgan should have also quoted Dr. Iakovlev's entire sentence, which reads: "The exact mechanisms of these late complications are yet to be understood, however factors accumulating over time need to be considered as primary contributors." Ex. B hereto, 9/21/17 Dep. 110:23-111:12.

Ironically, Plaintiffs, after criticizing Dr. Colgan for nitpicking Dr. Iakovlev, are themselves merely nitpicking Dr. Colgan. The fact remains that Dr. Iakovlev has conceded that mesh complications "are yet to be understood" and whether certain factors should be

“considered” is immaterial. As Dr. Colgan explained, “I think the better question is: What – why couldn’t Dr. ‘I’ find something to explain the pain specifically instead of hypothesizing, as he does without evidence, that this reaction is necessarily the central event in the development of symptomology.” *Id.* at 119:2-7. Plaintiffs are free to pursue this issue on cross-examination, and it certainly is not a matter that would render Dr. Colgan’s expert opinions inadmissible.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs’ motion to exclude Dr. Colgan’s opinions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this day, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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